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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,795	12/03/2004	Wenbin Dang	GPT-030.01	8669

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EXAMINER	
DICKINSON, PAUL W	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
11/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,795	DANG ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *6, 8-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7 and 10-23* is/are rejected.

7)☒ Claim(s) *16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 July 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/12/2004 and 1/14/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of formula VI in the reply filed on 8/14/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Objections

Claim 16 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Independent Claim 1 requires a composition comprising a biocompatible polymer and an antineoplastic agent. Dependent Claim 16 expands the limitations of Claim 1 to a composition without the polymer. Thus, Claim 16 fails to further limit Claim 1. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7, and 10-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent Claims 1 and 23 recite "said polymer comprises phosphorous-based linkages". The recitation of "phosphorous-

based linkages" renders the claims indefinite because it is unclear how far removed a linkage can be from a phosphorous linkage and still be considered a phosphorous-based linkage.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 and 10-18 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6537585 ('585). '585 discloses a method for treating brain tumors (a central nervous system neoplasm) of a patient comprising: instilling into an anatomic area of a patient affected by a central nervous system neoplasm a therapeutically effective amount of a composition comprising a biocompatible polymer and paclitaxel (an antineoplastic agent) (see abstract; col 3, line 31 to col 4, line 34; col 6, lines 32-41).

Although there is no specific examples of treating brain tumors, it is the position of the Examiner that, based on the brevity of the disclosure and short list of possible tumors to be treated, one of ordinary skill would instantly envision treating brain cancer with the disclosed composition.

Although '585 does not disclose all the characteristics and properties of the composition disclosed in the present claims, based on the substantially identical process using identical components, the Examiner has a reasonable basis to believe that the properties claimed in the present invention are inherent in the composition disclosed by '585. Because the PTO has no means to conduct analytical experiments, the burden of proof is shifted to the Applicant to prove that the properties are not inherent. ""[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)." MPEP § 2112.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

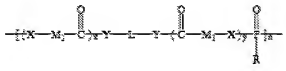
The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7, and 10-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5651986 ('986) in view of US 6166173 ('173). '986 discloses a method of treating brain cancer (a central nervous system neoplasm) of a patient comprising: instilling into an anatomic area of a patient affected by brain cancer a therapeutically effective amount of a composition comprising a biocompatible polymer and an antineoplastic agent (see col 3, line 64 to col 4, line 15; col 11, line 62 to col 12, line 20)). Paclitaxel is a preferred antineoplastic agent (see col 4, lines 10-15). The composition can be administered alone or in combination with, either before, simultaneously, or subsequent to, treatment using other chemotherapeutic or radiation therapy or surgery (see col 11, lines 62-67; col 12, lines 21-24; col 18, lines 14-16). '986 fails to disclose the polymer of Formula VI recited in Instant Claim 7.

'173 discloses a composition comprising a biocompatible polymer and an antineoplastic agent wherein the biodegradable polymer has the following formula:



Wherein

X = -O- or -NR'- where R' is H or alkyl;

M = (1) a branched or straight chain aliphatic group having from 1-20 carbon atoms or (2) a branched or straight chain, oxy-carboxy- or amino-aliphatic group having from 1-20 carbon atoms;

Y = -O-, -S-, or -NR'- where R' is H or alkyl;

L= any divalent branch or straight chain aliphatic group having from 1-20 carbon atoms; and

R = H, alkyl, alkoxy, aryl, aryloxy, heterocyclic or heterocycloxy residue.

(see abstract; col 6, line 40 to page 7, line 21). This polymer corresponds to Formula VI recited in Instant Claim 7. Paclitaxel is a preferred antineoplastic agent (see col 20, line 66 to col 21, line 5). The composition provides effective sustained drug release of the compound for a number of applications (see col 21, line 22 to col 22, line 33).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to incorporate the biodegradable polymer composition

disclosed by '173 into the method taught by '986, to afford a sustained release implant effective against brain cancer.

Although the references do not disclose all the characteristics and properties of the composition disclosed in the present claims, based on the substantially identical process using identical components, the Examiner has a reasonable basis to believe that the properties claimed in the present invention are inherent in the composition disclosed by '173. See MPEP § 2112.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

October 30, 2008